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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/611,409

06/30/2003

Steven M. Fischer

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05/31/2006

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/611,409	Applicant(s) FISCHER, STEVEN M.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-41 is/are pending in the application.
 4a) Of the above claim(s) 35-41 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 21-34 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/10/05, 8/14/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The applicant's response filed 4/27/2006 to the Office action has been entered. Claims 21-41 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 21-34 in the reply filed on 4/27/2006 are acknowledged.
2. Claims 35-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 4/27/2006.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 21-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,613,523. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 21-34 are drawn to a method of determining a nucleic acid sequence and claims 1-16 of U.S. Patent No. 6,613,523 are also drawn to a method of determining a nucleic acid sequence. The differences between both claims are that claims 1-16 of U.S. Patent No. 6,613,523 require a chamber, wherein a filtration membrane is attached to the chamber and the cdNTP which is not extended onto the single stranded DNA is washing through the filtration membrane. Although the instant claims 21-34 do not claim these limitations, the limitation is supported by the instant specification (See pg. 5, paragraph 3 and pg. 6, paragraph 1 and 2). Thus, the relation between the instant claims 21-34 and claims 1-16 of U.S. Patent No. 6,613,523 is as genus-species. The obviousness-type double patenting rejection is applicable.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 21-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 22-23 are vague and indefinite because of the phrase "cdNTP". It is unclear what is meant by the phrase. It is suggested to use complete name of the term.
- b. Claim 27 is vague and indefinite because it is unclear how the extension product is produced by a ligase in the presence of the oligonucleotide. Clarification is required.

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- c. Claims 25-27 are vague and indefinite because it is unclear how “an oligonucleotide” is used in the extension of the primer nucleic acid. Clarification is required.
- d. Claims 21-34 are vague and indefinite because the preamble recites a method of determining a nucleic acid sequence. However, the claims do not have an active step reciting how the nucleic acid sequence is determined. Clarification is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21-31 and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidt et al. (WO 99/02728, issued January 21, 1999).

Schmidt et al. disclose that a series of DNA fragments is provided by contacting a template in the presence of DNA polymerase with a mixture of nucleotides sufficient for hybridizing to the template for forming a second strand of DNA complementary to the template. The mixture comprises a set of four probes containing all four nucleotides for hybridizing to the template in which the nucleotide of each probe comprises a modified nucleotide which is capable of polymerizing to the second strand of DNA but blocked to prevent further polymerization and which is cleavably attached to the mass label. The mass label is identified by mass spectrometry for the modified nucleotide (See pg. 3, paragraph 5 and pg. 4, paragraph 1). The mass label is

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corresponding to a modified nucleotide so that the nucleotide present in the target template may be deduced (See pg. Paragraph 4). The cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). Ligating is also used to produce extended products (See pg. 12, paragraph 1 and 3). The cleavable tag is a 3' cleavable tag (See pg. 46, paragraph 5, fig. 4a and fig. 13) in which the cleavable tag is attached to the 3' end.

Schmidt et al. do not explicitly disclose the cleavable tag is an acid or base cleavable tag as recited in claims 29 and 30. However, Schmidt et al. disclose that the cleavage is done by photolysis or chemical cleavage (See pg. 12, paragraph 2, pg. 13, paragraph 2, pg. 46, paragraph 4). This teaching is inherent that the cleavable tag is an acid or base cleavable tag. Thus, the teachings of Schmidt et al. anticipate the limitations of Schmidt et al.

Summary

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. T.*
May 28, 2006

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

5/30/06